CERHR Evaluation Process

The NIEHS/NTP established the Center for the Evaluation of Risks to Human Reproduction (CERHR) to serve as an environmental health resource to health research and regulatory agencies, scientific and medical communities, and the public. CERHR provides timely, unbiased, scientifically sound evaluations of human and experimental evidence for adverse effects on development and reproduction caused by environmental chemicals, physical substances, or mixtures (collectively referred to as "substances") to which humans may be exposed.

CERHR has conducted health hazard assessments on more than 20 substances, published as NTP Monographs,[1] including industrial chemicals, drugs, and chemicals found in consumer products (e.g., phthalates and bisphenol A)[2] using an established, formal process (Figure 1). The scientific evaluation (part 2) has included convening an external expert panel to assess the scientific evidence and reach level-of-concern conclusions for adverse reproductive and/or developmental effects associated with human exposures. The expert panel report has been the primary document considered by the NTP in developing its level-of-concern conclusions in the NTP Brief. In 2004, in addition to public comment on the draft NTP Brief, the NTP added peer review to address guidance in the OMB Information Quality Bulletin for Peer Review (part 3).

On a limited basis, CERHR also has conducted state-of-the-science evaluations to examine the relevance of observed reproductive or developmental effects in laboratory animals in a particular area for prediction of adverse effects in humans, e.g., for thyroid toxicants. This type of evaluation has not resulted in development of the NTP Brief. In carrying out an evaluation of thyroid toxicants CERHR prepared a comprehensive literature review[3] and convened a workshop, with publication of a workshop report.[4]

Revised CERHR evaluation process

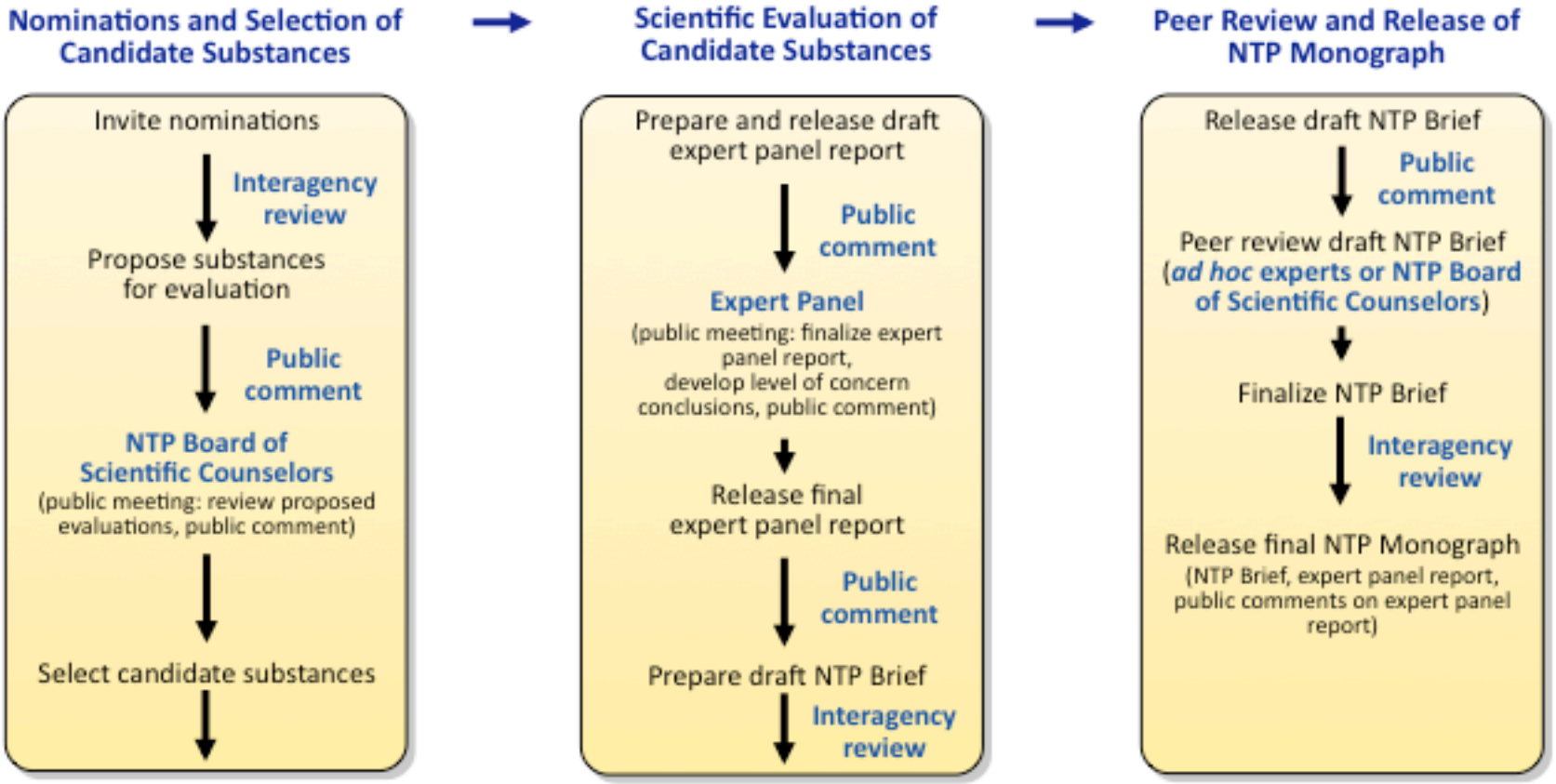
The recent addition of new scientific staff to CERHR has provided an opportunity for the NTP to re-examine the current evaluation process, focusing on strategies to enhance the scientific basis for development of CERHR products and maximize efficiency and utilization of resources. The NTP is revising the evaluation strategy for CERHR health hazard assessments, modifying the current process from a "one-path" model to one with the same general structure (Part 1: Nomination and Selection of Candidate Substances, Part 2: Scientific Evaluation of Candidate Substances, and Part 3: Review and Release of NTP Monograph), but with flexibility to tailor an evaluation to meet programmatic needs. Programmatic needs for an evaluation may vary depending upon the topic, scope, nature and extent of the literature (e.g., literature database is large versus a

[1] NTP Monograph contains the NTP Brief, expert panel report, and public comments on the expert panel report.
[2] CERHR expert panel and NTP Monographs available at http://cerhr.niehs.nih.gov/reports/index.html
[3] Choksi *et al*., Role of thyroid hormones in human and laboratory animal reproductive health. *Birth Defects Res B* 68:479-491, 2003.
[4] Jahnke, *et al*., Thyroid toxicants: assessing reproductive health effects. *Environ Health Perspect* 112:363-368, 2004.

small dataset and/or includes human, animal, and/or mechanistic information), degree of scientific complexity (e.g., findings inherently inconsistent and/or controversial), and public interest. Overall, with this strategy, CERHR would retain strengths of the current evaluation process (opportunity for external scientific input, public engagement at multiple points, interagency input, and peer review), and address weaknesses ("one-path" and limited flexibility).

The evaluation process would continue to be open and transparent (Figure 2). For each candidate substance under consideration, CERHR would develop a concept document that would include a presentation of a proposed process to conduct the evaluation. The concept document would be presented to the NTP Board of Scientific Counselors (part 1). Importantly, the flexibility to tailor an evaluation to meet programmatic needs would enable CERHR to use the most appropriate mechanism(s) in the scientific evaluation phase (part 2) to obtain external advice and address scientific issues (e.g., public listening sessions, expert panel, presentations by *ad hoc* scientific experts, or workshop). This input would be used by CERHR in development of the NTP Monograph. The NTP would continue to choose the most appropriate mechanism (*ad hoc* experts or NTP Board of Scientific Counselors) to carry out the peer review in part 3 of the process.

Current CERHR Evaluation Process



Revised CERHR Evaluation Process